UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456**
	ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO:	**JUDGE PATTI B. SARIS**
State of Montana v. Abbott Labs, Inc., et al., D. Mont. Cause No. CV-02-09-H-DWM	
State of Nevada v. American Home Products Corp., et al., D. Nev. Cause No. CV-N-02-0202-ECR	

REPLY MEMORANDUM OF BOEHRINGER INGELHEIM CORP., BEN VENUE LABORATORIES, INC. AND BEDFORD LABORATORIES TO MEMORANDUM IN OPPOSTION TO MOTION TO DISMISS STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND STATE OF NEVADA'S AMENDED COMPLAINT

The State of Montana and State of Nevada insist that they have adequately plead the who, what, when, where, and how of the alleged fraud, in compliance with both Federal Rule 9(b) and this Court's May 13, 2003 Order.[1] They have done no such thing. In fact, Plaintiffs largely repeat allegations this Court found in its prior decision to be lacking requisite specificity. *See In re Pharm. Indus. Ave. Wholesale Price Litig.*, 263 F.Supp.2d 172 (D.Mass. 2003).

Plaintiffs have not adequately identified the what (what about publication of AWP is fraudulent), the who (specific purchaser or company), or the how (how this so-called "spread" contributed to a fraud). Because Plaintiffs have not complied with either the Federal Rules, or this Court's May 13 Order, Defendants should be dismissed.

[1] *See* Mem. Opp. Def.-Spec. at 6; Joint Mem. Opp. at 20.

Neither Plaintiff Identifies the Fundamental Elements of the Fraud.

The District of Massachusetts has stated that the Rule 9(b) particularity requirement must be "strictly construed." *Curtis v. Duffy*, 742 F.Supp. 34, 38 (D.Mass. 1990). The fundamental purpose of 9(b) is to offer sufficient detail to enable a defendant to formulate a response.[2] A key component of this is to identify the essential facts that make a particular act fraudulent. *See Harrison v. Westinghouse Savannah River Co.*,176 F.3d 776, 789 (4th Cir. 1999) (dismissing on 9(b) grounds for, inter alia, failure to show *how* a signature was fraudulent).

Plaintiffs merely publish the so-called "spread" between a known AWP and a Plaintiff-adopted standard, and then attempt to conjure a cause of action by the repetitive assertion that this "spread" is a fraud. Such a device simply does not meet the requirements of 9(b). *Duffy*, 742 F.Supp. at 38.

***Parens Patriae* Does Not Relieve the States of their Pleading Obligations.**

Plaintiffs argue that "no case has required the States to identify in a complaint all citizens they are acting on behalf of" and that "Boehringer cites no such case."[3] However, it is elementary that to prepare a defense to fraud, a defendant must be informed of who was defrauded and how. The mere fact that a state sues on behalf of its citizens does not relieve it of this duty. *In re Tobacco/Gov'l Health Care Costs Litig.*, 83 F.Supp.2d 125, 135 n.8 (D.D.C. 1999) (Country of Guatemala's RICO complaint brought in *parens patriae* capacity capable of being dismissed for failure to plead fraud with particularity).

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[2] 5 Wright & Miller, Federal Practice & Procedure, § 1296, at 580 (2d ed. 1990) (Noting that among the justifications for 9(b) is the fact that "[F]raud and mistake embrace such a wide variety of potential conduct that a defendant needs a substantial amount of particularized information about plaintiff's claim in order to enable him to understand it and effectively prepare his response.")

[3] Mem. Opp. Def.-Spec. at 35.

Boehringer Ingelheim Corporation Should Be Dismissed From this Suit Because the Pleading Does Not Meet Rule 9(b) Requirements, and Because Discovery for Personal Jurisdiction Purposes is Irrelevant to Standing.

Finally, Plaintiffs claim that the mere fact Boehringer Ingelheim Corporation is named should subject it to personal jurisdictional discovery.[4] As an initial point, the First Circuit has stated that the particularity requirement of Rule 9(b) is specifically designed to deter plaintiffs who file suit in the hope that something will arise during discovery. *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996). Second, discovery on the issue of personal jurisdiction is inapt where the defense is one of standing. Standing has an Article III jurisdictional component that must be adequately pled *before* the suit can be entertained. *Coyne v. Am. Tobacco Co.*, 183 F.3d 488, 494 (6th Cir. 1999).[5]

Plaintiffs had plenty of time, and the entire resources of the state, to identify which Defendants manufacture which drugs. In fact, a short trip to the library would have produced the Physician's Desk Reference, which contains the name and manufacturer for many drugs in this suit.[6] They failed to do so; for that reason, as well as for the reasons stated above and in the Consolidated Reply, the Plaintiffs' Complaints should be dismissed.

Respectfully submitted,

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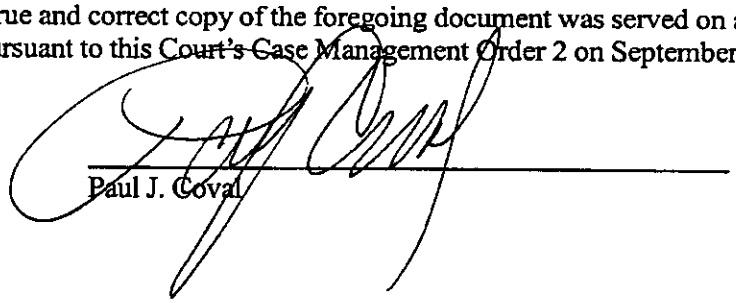
[4] Plaintiffs erroneously state that "Boehringer claims that one of its *subsidiaries* does not engage in the manufacture of any of the drugs at issue." Mem. Opp. Def.-Specific. at 35. This is inaccurate. Defendants only state that Boehringer Ingelheim Corporation does not manufacture any of the drugs at issue. *See* Def. Mem. at 5.

[5] "A plaintiff bears the burden of demonstrating standing and must plead its components with specificity." (citing *Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982)).

[6] *See* Physicians Desk Reference (57th ed. 2003).

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document was served on all enrolled counsel via Verilaw pursuant to this Court's Case Management Order 2 on September 15, 2003.



Paul J. Coval

#7

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs, Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM *State of Nevada v. American Home Prods. Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR	

B. BRAUN OF AMERICA INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT

Nothing in Montana's and Nevada's Opposition refutes the fundamental facts mandating dismissal of B. Braun of America Inc. ("BBA"). BBA was not properly served, and the Court lacks personal jurisdiction over BBA. In addition, plaintiffs failed to adequately address the other fatal deficiencies mandating BBA's dismissal.

I. BBA Must Be Dismissed for Lack of Personal Jurisdiction and Improper Service.

The States do not dispute that BBA was ***not properly served*** under the laws of Montana and Nevada; instead, they incorrectly argue that Fed. R. Civ. P. 4(e) authorizes service under Massachusetts law. But the Judicial Panel on Multidistrict Litigation has held that "proper service must still be made on each defendant pursuant to the rules of the transferor court even after a transfer under 1407." *In re Lib. Eds. of Children's Books*, 299 F. Supp. 1139, 1142 (J.P.M.L. 1969); Charles A. Wright, *et al.*, 15 Fed. Prac. & Proc. Juris. 2d § 3865 (2003).[1] Because BBA was improperly served under applicable law, the States' claims must be dismissed.

Moreover, the Court cannot exercise personal jurisdiction over BBA. BBA does not itself make, manufacture, sell, or distribute any drugs at all, in any State. Nor does it share an "identity of interest" (*see* Opp. at 44), a concept plaintiffs do not even claim that courts have accepted.[2] In short, the States have no basis for suing BBA. They cannot rest on mere allegations to establish personal jurisdiction, especially in the face of uncontested evidence that BBA does not do business in Massachusetts, Nevada, or Montana. *Barrett v. Lombardi*, 239 F.3d 23, 27 (1st Cir. 2001); *Dole Food Co. v. Watts*, 303 F.3d 1104, 1108 (9th Cir. 2002).

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1 Even if Massachusetts law applied, service by mail would be improper because, as the DiNardo Affidavit makes clear, the Massachusetts' long-arm statute has not been satisfied. *See* Mass. Gen. L. 223A § § 3,4,6.

2 The States' reliance on excerpts from alleged "Braun" documents are insufficient to claim an "identity of interest" since those documents were neither produced by BBA nor relate to BBA.

II. The States Concede that All Best Price and Average Manufacturer Price ("AMP") Claims Must Be Dismissed.

In its motion to dismiss, BBA pointed out the inherent illogic of the States' claims: Medicaid rebates for non-innovator, multiple-source drugs are set at 11% of their respective AMPs, not based on any reported "Best Prices," *see* 42 U.S.C. § 1396r-8(c)(3). Thus, allegations relating to Best Prices are irrelevant to the claims against BBA. Nor do the "AMP" claims make sense. If a manufacturer were to improperly raise its AMPs, the only result would be ***increased*** rebates, which benefit the States, not injure them. The States did not even address this argument.

III. The States' Deceptive Trade Practices Claims Must Be Dismissed as Time-Barred.

The States' Deceptive Trade Practices claims are barred by the applicable statutes of limitations.[3] Section 1202.3 of Nevada's Medicaid Manual establishes that it was on notice of – and began using – the DOJ pricing for products in May 2000. Thus, Nevada has not suffered injury after this period, and injuries incurred prior to that time are barred by Nevada's three-year statute of limitations.[4] Similarly, Montana's Deceptive Trade Practices claims are time-barred. Montana does not dispute that the applicable statute of limitations is two years. Montana's invocation of the "discovery rule" does not preclude dismissal, since it was aware of the DOJ report. Thus, all such claims must be dismissed.

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[3] Nevada correctly notes that its Medicaid Fraud claims are subject to a four-year statute of limitations, and its state RICO claims have a five-year statute of limitations. The Medicaid Fraud claims, however, do not state a claim to the extent they are based on the alleged "Best Price" and "AMP" manipulation. *See* part II, *supra*. The Nevada RICO claims fail for the same reasons the federal RICO claims fail in the Amended Master Consolidated Class Action Complaint. Moreover, to the extent that Nevada was on notice of such claims prior to the publication of the DOJ Report, those claims are time-barred.

[4] Nevada argues a "factual" issue exists concerning whether it disregarded its own regulations by failing to use the DOJ-reported prices. But there is no factual allegation that Nevada actually disregarded its own regulations. *See Associated Gen. Contractors of Cal. v. California State Counsel of Carpenters*, 459 U.S. 519, 526 (1983) (Under 12(b)(6), "it is not ... proper to assume that the [defendant] can prove facts that it has not alleged. . . .") Rather, the Complaint clearly alleges that Medicaid reimbursement after May 2000 was based on the DOJ report.

IV. Montana's Medicaid Reimbursement Claims Must Be Dismissed.

As a matter of law, Montana's Medicaid reimbursement is set at the *lowest* of several options, many of which are unrelated to AWP. *See* Mont. Admin. R. 37.86.1101; Mont. Admin. R. 37.86.1105; 42 C.F.R. § 447.331(b). Montana does not address this argument. Rather, it simply rests on its vague allegation – unsupported by any legal authority or specific factual allegation – that Montana made AWP-based payments. But Montana's argument either rests on a misinterpretation of Medicaid regulations, which the Court need not accept; or, because plaintiffs have not identified any actual fraudulent transactions, is unsupported by particularized factual allegations as required by Rule 9(b). *See New England Cleaning Servs. v. American Arbitration Ass'n*, 199 F.3d 542, 545 (1st Cir. 1999) ("court is not required to accept legal conclusions as true when considering a motion to dismiss").[5]

CONCLUSION

For the foregoing reasons, as well as those argued in the memoranda submitted jointly by defendants or by other defendants individually, B. Braun of America Inc. urges that it be dismissed from the cases brought by Montana and Nevada.

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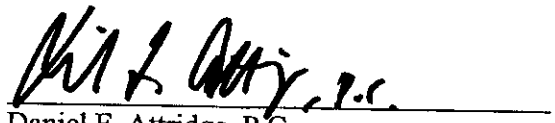
[5] BBA also moved to dismiss the States' *parens patriae* claims. In response, Montana concedes that it cannot bring any claims on behalf of its citizens based on Medicaid co-payments. Opp. at 40. Any remaining *parens patriae* claims should, as BBA explained in a footnote, be dismissed for lack of standing. Plaintiffs' response – that Fed. R. Civ. P. 23 does not apply to such claims – misses the point. The fact remains that Montana and Nevada citizens are encompassed by the putative class action, so a *parens patriae* action is duplicative and unnecessary. *See, e.g., People of the State of New York v. Seneci*, 817 F.2d 1015, 1017 (2nd Cir. 1987) (dismissing as moot Attorney General's claim for injunctive relief where the remedy had been granted in a parallel state court case). Because the citizens are capable of seeking monetary damages on their own, individually or through the putative class action, the States lack prudential standing. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 600 (1982) (States lack *parens patriae* standing where they are merely "stepping in to represent the interests of particular citizens who, for whatever reason, cannot represent themselves"); *Pennsylvania v. New Jersey*, 426 U.S. 660, 665 (1976) ("a State has standing to sue only when its sovereign ... interests are implicated and it is not merely litigating as a volunteer the personal claims of its citizens; rejecting *parens patriae* suit where it "represents nothing more than a collectivity of private suits").

Dated: November 7, 2003

Respectfully submitted,



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#8

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO:	Master File No. 01-CV-12257-PBS
State of Montana v. Abbott Laboratories, Inc. et al., D Mont. Cause No. CV-02-09-H-DVM	Judge Patti B. Saris

DEY, INC.'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ITS MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT

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I. INTRODUCTION

Defendant Dey, Inc. ("Dey") submits this reply memorandum in further support of its motion to dismiss all claims asserted against it by the State of Montana ("Montana") in the Second Amended Complaint (the "Complaint").[1]

II. ALL MULTIPLE-SOURCE DRUG CLAIMS SHOULD BE DISMISSED

Defendants demonstrated in their opening briefs that all claims concerning multiple-source drugs should be dismissed since competition on the basis of AWP inflation – the central allegation of the Complaint – is impossible under the applicable regulations. Montana fails to show why Defendants' multiple-source drug arguments should be rejected. Indeed, conceding that Defendants accurately depicted the metric by which reimbursement is calculated for multiple-source drugs, Montana is reduced to arguing that: (i) AWP is an "essential ingredient" of the "reimbursement formula" under Medicare and Medicaid (Def. Spec. Mem. at 11), (ii) drug manufacturers act in "unison" in "elevating" AWP (*id.* at 11-12), and (iii) large "spreads" somehow indicate the workings of a fraudulent scheme (*id.* at 13).[2] None of these arguments can save Montana's claims.

First, the mere fact that reimbursement under Medicare or Medicaid is related to AWP is meaningless. The issue is not whether AWP is somehow connected to the reimbursement formula, but whether, consistent with Montana's theory of its case, individual Defendants can compete on the basis of AWP inflation of multiple-source drugs. As this Court previously recognized, the reimbursement scheme under Medicare Part B does not permit such competition. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp.2d 172, 194 (D. Mass. 2003). Moreover, under

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[1] Dey also joins in the Consolidated Reply Memorandum In Support of Defendants' Motion To Dismiss The State of Montana's Second Amended Complaint And The State of Nevada's Amended Complaint (the "Consolidated Reply"), which is incorporated herein by reference.

[2] Montana incorrectly contends that Defendants' argument regarding the impossibility of competition on the basis of AWP "utterly ignores" the allegations of the Complaint. The Court is not required to turn a blind eye to the regulations which render Defendants' alleged "scheme" impossible. *See Shwarz v. United States*, 234 F.3d 428, 435 (9th Cir. 2000) (holding that a court need not accept as true "allegations that contradict facts that may be judicially noticed by the court"); *Pleva v. Norquist*, 36 F. Supp. 2d 839, 843 (E.D. Wis. 1999) (holding that, on a motion to dismiss, "the court may take judicial notice of matters of public record such as state statutes, city charters, and city ordinances").

Medicaid, Montana concedes that it uses a maximum allowable cost ("MAC"), which is a flat reimbursement rate, for certain multiple-source drugs. Such a flat reimbursement rate is entirely inconsistent with competition based on the so-called "spread". Therefore, all claims based on reimbursement of drugs to which Montana applies a MAC should be dismissed.

Second, Montana points to absolutely nothing to support the notion that "drug makers act in unison by elevating the AWP for all generic drugs" and that "this 'leap frogging' of *increasing* AWPs" results in multiple-source drugs allegedly having some of the "highest spreads of any drug". (Def. Spec. Mem. at 11, 13) (emphasis added). Indeed, as applied to Dey, such allegations directly contradict the allegations in Appendix A to the Complaint. In Appendix A, Montana alleges that the AWPs for each of the drugs attributed to Dey either stayed the same or went down over time.

Finally, the existence of a "spread" proves absolutely nothing. Montana points to nothing which would compel the Court to hold that the mere existence of a spread proves that manufacturers manipulate AWP to "gain or maintain a competitive advantage." (Def. Spec. Mem. at 13.)

III. MONTANA'S MERE REFERENCE TO DEY'S ACTION AGAINST FIRST DATABANK CANNOT SAVE MONTANA'S CLAIMS FROM BEING DISMISSED

Time and again Montana refers to and quotes from Dey's complaint in an action Dey recently filed against First DataBank (the "FDB Action"). Montana drags the FDB Action into service to draw attention from the weaknesses of its arguments in a last-ditch effort to save the Complaint from dismissal. As Dey noted in its opening memorandum of law, the FDB Action is irrelevant.

First, as Montana implicitly concedes, the FDB Action has absolutely nothing to do with Medicare Part B reimbursement in Montana. Second, even in the Medicaid context, the FDB Action stands for much less than Montana urges. Indeed, Montana completely glosses over the fact that the FDB Action has nothing to do with reimbursement for drugs under the Montana Medicaid program. This distinction is important because Montana seeks to use the general allegations of the FDB Action to prop up its Montana-specific claims of fraud. For example, Montana points to nothing in the FDB

Action which speaks to how Montana or Medicare reimburses for multiple-source drugs, but instead relies completely on general allegations made by Dey in the FDB Action.

IV. MONTANA'S RELIANCE UPON MANUFACTURED EVIDENCE SHOULD BE REJECTED

As Dey noted in its opening memorandum, the Complaint contains a table which Montana alleges is "excerpted" from a Dey document. (Complaint ¶ 398, Table 1.) As Dey demonstrated, the table contains a fabricated column. Incredibly, caught manufacturing evidence, Montana resorts to the argument that this type of conduct is of no moment since the math it used to create the fabrication is accurate. On the contrary, the fabricated "spread" column creates the misimpression that Dey distributed this document as part of a blatant attempt to "market the spread" of its drugs, thereby lending apparent support to Montana's primary argument that Defendants manipulate AWP to gain a competitive advantage based on the "spread". This use of manufactured evidence should be rejected.

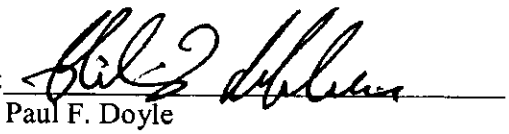
V. CONCLUSION

For the foregoing reasons, as well as those stated in the Consolidated Reply and the individual memoranda of other Defendants addressing common issues, the Court should dismiss the Complaint as to Dey with prejudice.

Respectfully submitted,

KELLEY DRYE & WARREN LLP

Dated: November 7, 2003

By: 

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#9

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456**
THIS DOCUMENT RELATES TO	**Master File No. 01-CV-12257-PBS**
State of Montana v. Abbott Labs., Inc., et al., D. Mont. Cause No. CV-02-09-H-DWM	**Judge Patti B. Saris**

REPLY MEMORANDUM IN SUPPORT OF GLAXOSMITHKLINE'S MOTION TO DISMISS

Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK"), respectfully submits this reply memorandum in support of its motion to dismiss the State of Montana's Second Amended Complaint ("MC"). In the event the claims against GSK are not dismissed for the reasons stated in the Consolidated Motion to Dismiss, they should be limited to those involving reimbursement for Kytril and Zofran under Medicare Part B because these are the only GSK drugs for which the State makes any particularized allegations of fraud.

Contrary to the State's assertions, the State is not excused from meeting the 9(b) standard and is required -- at a minimum -- to allege a fraudulent spread for each of the drugs it wants to keep in the case. Relying on *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001), the State argues that it need only allege the general "circumstances of the fraud" to satisfy Rule 9(b). The State's reliance on *Parke-Davis* is misplaced. In that case, this Court considered plaintiff's claims drug-by-drug, and indeed dismissed claims relating to one drug where only a "general scheme" was alleged without any specific facts relating to that

drug. *Id.* at 47-50. Thus, even under the *Parke-Davis* analysis, the claims relating to drugs other than Kytril and Zofran should be dismissed because the State has not alleged specific facts concerning these drugs.[1]

The State claims that it is sufficient to allege only the published AWP and that it should be excused from having to allege a fraudulent spread for the GSK-manufactured drugs named in the MC because information relating to the actual prices of these drugs are exclusively in GSK's control. This argument is meritless. It is well-established that the relaxation of pleading requirements is inappropriate where relevant information is held by the plaintiffs. *See Efron v. Embassy Suites (P.R.), Inc.*, 223 F.3d 12, 16 (1st Cir. 2000) (relaxation of pleading standards where information is in defendant's sole possession is inapplicable where the information is held by plaintiffs). Here, the State concedes that it can allege an estimated spread based on information in its possession. Mem. in Opp. to Def. Specific Mem. on Motions to Dismiss at 10 n.9. Indeed, as the State points out, it has done so for numerous non-GSK drugs.

Finally, the State's argument that Rule 9(b) is satisfied because the MC "include[s] detailed allegations of examples of the spread for virtually each manufacturer" is inapplicable any to GSK other than Kytril and Zofran. MC ¶ 64. The State has completely failed to allege even an estimated spread or any other conduct for any GSK drug other than Kytril and Zofran.

Indeed, the only places in the MC (other than the Appendix) that any GSK drug other than Kytril and Zofran is specifically mentioned are ¶¶ 423 and 456. Paragraph 423 is a

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[1] The State's reliance on *In re Xcelra.com Sec. Litig.*, 2002 U.S. Dist. LEXIS 7400 (D. Mass. Mar. 8, 2002) is similarly misplaced because the State has not quoted from or cited to any "supporting documentation" relating to any GSK drug other than Kytril or Zofran.

supposedly non-exclusive list of GSK drugs for which GSK has supposedly stated fraudulent AWPs. There are no specifics as to any of these drugs except their therapeutic category and usage. Paragraph 456 merely alleges that in 2000 and 2001 the published AWPs for the listed GSK drugs were increased. The State does not identify any spread or any marketing of the spread for any of these drugs -- let alone one that is substantially lower than the published AWPs. Moreover, the State does not identify any particular false statements by GSK with respect to the AWPs for these drugs. Merely alleging that the published AWP for a particular drug was increased is a far cry from alleging fraud with particularity under Rule 9(b). The State should not be permitted to engage in massive discovery into the pricing for all of GSK's drugs based on nothing more than two conclusory allegations that the AWPs for these drugs were fraudulent. The purpose of Rule 9(b) is to prevent such fishing expeditions.

Respectfully submitted,

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#10

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris Hearing Date: December 12, 2003
THIS DOCUMENTS RELATES TO: *State of Montana v. Abbott Labs., Inc. et al.*, (D. Mont. No. CV-02-09-H-DWM) *State of Nevada v. American Home Products Corp., et al.*, (D. Nev. No. CV-N-02-0202-ECR)	

REPLY IN SUPPORT OF IMMUNEX CORPORATION'S MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT

INTRODUCTION

Despite the Court's admonition that "[w]e're going to go drug by drug," Tr. of Oral Argument at 74 (Jan. 13, 2003), the States' brief refers largely to generalized allegations that pertain only to two Immunex products, both of which are multiple-source drugs. The Court should reject the States' attempt to bootstrap their claims about multiple-source drugs into a broader attack upon every product that Immunex ever sold. Because the States' allegations violate the purpose of Rule 9(b) and are at odds with the unique reimbursement system for multiple-source drugs, the Court should dismiss these claims with prejudice.

I. The States Violate Rule 9(b) by Failing to Identify a Single Specific Best Price Claim Against Immunex.

The Best Price claims against Immunex contravene all three of Rule 9(b)'s purposes: "(1) to place the defendants on notice and enable them to prepare meaningful responses; (2) to preclude the use of a groundless fraud claim as a pretext to discovering a wrong or as a 'strike suit'; and (3) to safeguard defendants from frivolous charges which might damage their reputations." *New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 289 (1st Cir. 1987). The handful of paragraphs in the States' Complaints that relate to Best Price claims make generalized allegations about "drug manufacturers," but allege nothing specific to Immunex. *See* Mont. Compl. ¶¶ 612-616; Nev. Compl. ¶¶ 392-397.

The States argue that Immunex is "on notice as to the Best Price allegations" from the AWP-related allegations and that Immunex distributed "examples of free products." States' Opp. to Defendant-Specific Memo. ("States' Opp.") at 47. This is far from adequate notice, and looks more like a pretext for discovery on claims unrelated to the core AWP claims at issue. The States' argument ignores the fundamental difference between reimbursement of providers on the basis of AWP (in the Medicare Part B program and certain commercial

payors) and rebate payments payable to State Medicaid agencies on the basis of Best Price and Average Manufacturer Price (for drugs covered by the Medicaid program). As to the "free products" allegation, it is woefully unspecific and does not allege any illegal conduct. The States do not allege (because it is not true) that Immunex encouraged its customers to resell these samples, or to bill these samples to any government or private payor.

II. The AWP-Related Claims Against Immunex Also Violate 9(b).

The States' AWP allegations also contravene the purposes of Rule 9(b), particularly as to the claims relating to Immunex's single-source products, Leukine®, Novantrone®, and Thioplex®.[1] The States contend that "[a]s to Immunex's single source drugs, the complaints set forth the general scheme," States' Opp. at 47, but the States have simply made the boilerplate allegations that the published AWPs for Immunex's single-source products were fraudulent. The allegations of "inflated AWPs, with estimated spreads," States' Opp. at 46, relate only to Immunex's multiple-source products leucovorin calcium and methotrexate sodium. *See* Mont. Compl. ¶ 475, Nev. Compl. ¶ 296. The Court should reject the States' attempt to bring claims against Immunex's single-source products into the case, especially considering that the States possess information about actual prices from the voluminous documents that Immunex produced regarding all five drugs at issue.

The States also play loose with the law on what is required under Rule 9(b). The States assert that Rule 9(b) is satisfied if the plaintiff simply alleges that "'the plaintiff acted upon it to his damage.'" *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 284 (3rd Cir. 1992). In fact, that is but one part of that case's five-part Rule 9(b) test:

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[1] As of 2001, a generic equivalent of Immunex's Thioplex® (thiotepa) was available for sale.

> (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage.

Id. Plaintiffs do not meet this test, particularly as to Immunex's single-source products.

III. The Court Should Dismiss the States' AWP Claims Relating to Multiple-Source Drugs.

Immunex argued that the States' *parens patriae* claims relating to multiple-source drugs are identical in substance to claims asserted by the private plaintiffs in the AMCC, and urged the Court to dismiss these claims for the reasons set forth in the consolidated memorandum in support of defendants' motion to dismiss the AMCC. The States respond by focusing on the Immunex-specific briefing to dismiss the AMCC for another reason, the lack of a plaintiff purchaser for each drug. The consolidated defense briefing outlined the unique reimbursement scheme under Medicare Part B for multiple-source drugs, which is based on the median of all AWPs, and thus prevents competition on the basis of a single drug's AWP.

The States' references to "inflated" spreads on particular multiple-source drugs have no bearing on the actual amount paid by the States or their residents, which the States have also failed to plead with specificity. Similarly, in the Medicaid context, these spreads are irrelevant unless they pertain to the *lowest AWP published*, the basis for reimbursement under the States' Medicaid programs. Mont. Compl. ¶ 188; Nev. Compl. ¶ 151. The States' Complaints fail to allege that Immunex's allegedly fraudulent AWPs for its multiple-source drugs were the lowest AWPs published and thus the basis for reimbursement by the States.

CONCLUSION

For the foregoing reasons and those set forth in the consolidated reply and individual defendant briefs, the Court should dismiss the States' claims against Immunex with prejudice.

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#11

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257 PBS
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Laboratories, Inc., et al.* D. Mont. Cause No. CV-02-09-H-DWM *State of Nevada v. American Home Products Corp., et al.* D. Nev. Cause No. CV-02-0202-ECR	Judge Patti B. Saris

REPLY MEMORANDUM OF LAW OF NOVARTIS PHARMACEUTICALS CORPORATION IN SUPPORT OF ITS MOTIONS TO DISMISS THE SECOND AMENDED COMPLAINT OF THE STATE OF MONTANA AND THE AMENDED COMPLAINT OF THE STATE OF NEVADA

INTRODUCTION

In its moving Memorandum of Law ("NPC Mem."), Novartis Pharmaceuticals Corporation ("NPC") established that the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint must be dismissed as to NPC for failure to plead fraud and state a claim under Fed. R. Civ. P. 9(b) and 12(b)(6) because: (1) no AWPs are pled for nine drugs for which NPC is alleged to have inflated AWPs; (2) no specific facts are pled as to how the identified AWPs for NPC drugs are allegedly fraudulent; (3) no Best Price allegations specific to NPC are pled; and (4) no facts specific to NPC are pled in connection with Nevada's racketeering claim. As demonstrated below, nothing in Montana and Nevada's (together, the "States") joint opposing memoranda alters this conclusion. NPC joins in and incorporates by reference defendants' consolidated reply memorandum and reply memoranda of individual defendants.

ARGUMENT

I. THE STATES NOW CONCEDE THAT THEIR CLAIMS AGAINST NPC REGARDING NINE SPECIFIC DRUGS MUST BE DISMISSED.

The States assert that Appendix A to their complaints identifies each drug and each alleged false AWP upon which they base their claims. State of Montana's and State of Nevada's Memorandum in Opposition to Defendant-Specific Memoranda on Motions to Dismiss ("Opp. Mem.") at 3-4. NPC previously demonstrated (NPC Mem. at 3-4), and the States now admit (Opp. Mem. at 48), that nine specific drugs – Diovan, Diovan HCT, Elidel, Famvir, Focalin, Rescula, Votaren Opthalmic, Zaditor and Zelnorm – alleged to have been "subject to [AWP] manipulation" by NPC (Mont. Cplt. ¶501; Nev. Cplt. ¶322) are *not* included in Appendix A and no AWP has been identified for these drugs. As the States agree, this Court has "required identification of the [allegedly] inflated AWP" for each drug at issue. Opp. Mem. at 3, *citing this Court's Order reported at In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172 (D. Mass. 2003). Accordingly, all claims against NPC relating to the nine drugs omitted from Appendix A must be dismissed.

II. THE STATES DO NOT PLEAD SPECIFIC FACTS AS TO NPC DRUGS THAT SATISFY FED. R. CIV. P. 9(b) OR 12(b)(6).

NPC demonstrated (NPC Mem. at 4-5) that the allegations in the States' complaints relating to the remaining NPC drugs do not satisfy Fed. R. Civ. P. 9(b) or 12 (b)(6). In opposition, the States claim that

"general allegations of the industry-wide misuse of AWP" (Opp. Mem. at 48) – buttressed by specific "typical" examples relating to "almost every" or "most" *other* defendants – suffice to support their claims against NPC. *E.g.*, Opp. Mem. at 4, 6-10, 16. In cases involving multiple defendants, however, the complaint must inform each defendant of the specific alleged fraud by that particular defendant. *See, e.g., Vicom, Inc. v. Harbridge Merchant Servs., Inc.*, 20 F.3d 771, 778 (7th Cir. 1994). Notably, the States do not attempt to plead any "typical" examples of AWP fraud relating to NPC. Rather, the sole "specific" allegation as to NPC is that in late 2000 and 2001 the published AWPs for certain NPC drugs increased in amount. Merely alleging that published AWPs changed does not and cannot satisfy Fed. R. Civ. P. 9(b)'s mandate to plead fraud with particularity.[1] Thus, notwithstanding this Court's express instruction, the States have failed to "particularize . . . exactly what the fraud is [by NPC]." *In re Average Wholesale Price Pharm. Litig.*, Tr. of Oral Argument at 74 (Jan. 13, 2003).[2]

III. THE STATES DO NOT PLEAD BEST PRICE ALLEGATIONS SPECIFIC TO NPC.

As is true for their AWP allegations (Point II, *supra*), the States effectively admit that their broad general allegations of Best Price-related misconduct by "all defendants" only satisfy pleading requirements when combined with defendant-specific examples of such misconduct. Opp. Mem. at 16-17. Yet, as NPC demonstrated (NPC Mem. at 3), there is not a single allegation specific to NPC in either Montana's or Nevada's complaint in connection with the Best Price fraud claim. Significantly, while conceding that they are required to provide defendant-specific "examples of the ***how***, ***what*** and ***when***" of an allegedly fraudulent scheme, the States do not respond directly to NPC. *Id.* at 3 (emphasis in original), *citing U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (Saris, J.). Instead, they refer the Court to Section III.D of their

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[1] The States identify one purported NPC-specific government investigation, allegedly relating to the NPC drug Aredia (Mont. Cplt. ¶503; Nev. Cplt. ¶324). However, merely alleging the existence of a government investigation in connection with AWP does not suffice under Fed. R. Civ. P. 9(b). Moreover, Aredia: (i) is *not* an NPC drug for which the States purport to seek relief, and (ii) is *not* included in Appendix A, which the States claim identifies the allegedly fraudulent AWPs of drugs upon which they base their claims.

[2] Contrary to the States' assertions, NPC has not claimed that they must set forth "true" average wholesale prices. Rather, NPC asks this Court to hold the States to the standard they concede applies – *i.e.*, they must plead the "who, what, where, when and how" of any alleged fraud as to NPC (Opp. Mem. at 3, 6) and fail to do so here.

memorandum (Opp. Mem. at 49), even though that section does not point to *any* allegations specific to NPC. In short, the States do not deny that they have not pled such specifics as to NPC, including, fundamentally, ***how*** NPC allegedly misstated Best Price. The States thus do not, and cannot, dispute that they nowhere plead how or to whom NPC allegedly provided free samples of drugs, volume discounts, rebates, education grants, or allegedly engaged in any other conduct that purportedly resulted in misreporting to the Medicaid program or even that NPC has been the subject of any government inquiry relating to Best Price fraud. Nor do the States contest that none of the alleged "exemplary misconduct" pled (Mont. Cplt. ¶616-33; Nev. Cplt. ¶397-403) involves NPC. Thus, in the absence of even a single specific example in connection with the alleged Best Price scheme relating to NPC, the States' general allegations of industry-wide behavior fail to meet the requirements of Fed. R. Civ. P. 9(b) and 12(b)(6) as to NPC. *See also* Defendants' Consolidated Reply Memorandum, Point I.C.

IV. NEVADA DOES NOT PLEAD SPECIFIC FACTS AS TO ITS RACKETEERING CLAIM THAT SATISFY FED. R. CIV. P. 9(b) OR 12(b)(6).

Nevada's Count IV racketeering claim, which also is subject to Fed. R. Civ. P. 9(b) pleading mandate (NPC Mem. at 5), relies upon the same general allegations as the States' other AWP- and Best Price- related claims. For all of the same reasons set forth above in Points II and III, Nevada thus fails to plead racketeering predicate acts as to NPC with the specificity required and otherwise fails to state a claim upon which relief may be granted. The racketeering claims also must be dismissed because Nevada lacks standing to bring such claims and fails to allege a cognizable enterprise. Defendants' Consolidated Reply Memorandum, Point II.B.

CONCLUSION

For the foregoing reasons, as well as those set forth in the moving memoranda and defendants' consolidated and individual reply memoranda, the Court should dismiss with prejudice all claims as to NPC.

Dated: Boston, Massachusetts
November 7, 2003

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